



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,355	03/03/2004	Bruno Pfeiffer	SERVIER 396 PCT	5116

25666 7590 05/09/2006

THE FIRM OF HUESCHEN AND SAGE
SEVENTH FLOOR, KALAMAZOO BUILDING
107 WEST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,355

Applicant(s)

PFEIFFER ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 03/31, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,23,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/03/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This application claims benefit of the foreign application: FRANCE 00/08973 with a filing date 07/06/2000.
2. Claims 14-26 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on April 03, 2006, has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of Group I claims 14, 23 and 25-26 in the reply filed on April 12, 2006, is acknowledged. The traversal is on the ground(s) that the disclosure demonstrates the criticality of the instant process (i.e., Group II) with respect to yield and purity of the resulting single α -crystalline form of perindopril tert-butylamine. This is not found persuasive and the reasons are given, *infra*.

It is noted that restriction to one of the Groups I-III is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category, e.g. Compounds, Methods of Use, Methods of Making, etc.

Each of Groups I-III is distinct and independent product, processes of making or methods of use one from the other on the basis of structure defined in the claimed products processes of making and methods of use as and they differ in elements, starting materials, reaction conditions, dose, and administration bonding arrangement

Art Unit: 1626

and chemical property to such an extent that a reference anticipating processes of any one group would not render another group obvious. Absent factual evidence to the contrary, each is a different invention.

Groups I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product having indole moiety (i.e., treating heart disease) as claimed can be practiced with another materially different product of McComsey et al. US 6,365,617. Claims 15-21, 22 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference (i.e., Guez et al. US 6,653,336) is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 14, 23 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincent et al. US 4,914,214.

Applicants claim a crystalline form of the compound of formula (I), i.e., perindopril of tert-butylamine salt, and its pharmaceutical compositions, see claim 14, 23, and 25-26. It is noted that the preamble of the characteristics of the X-ray diffraction data does not obtain any patentability weight.

Vincent et al. disclose the same instant compound of same tert-butylamine salt in crystalline form, see column 10, lines 10-31. Therefore, Vincent et al. crystalline form of the same compound perindopril of tert-butylamine salt clearly anticipate the instant claim 14. The dependents claims 23 and 25-26 of claim 14, drawn to compositions, are also rejected along with claim 14 under 35 U.S.C. 102(b).

Claims 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Guez et al. US 6,653,336.

Applicants claim a crystalline form of the compound of formula (I), i.e., perindopril of tert-butylamine salt, and its pharmaceutical compositions comprising a compound,

i.e., perindopril of tert-butylamine salt, and a diuretic (i.e., indapamide), see claims 25-26. It is noted that the preamble of the characteristics of the X-ray diffraction data does not obtain any patentability weight.

Guez et al. disclose a pharmaceutical composition tablet comprising a compound, i.e., perindopril of tert-butylamine salt, and a diuretic (i.e., indapamide), see column 4, Examples 1-2. Therefore, Guez et al. pharmaceutical compositions clearly anticipate the instant claims 25-26.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also see M.P.E.P. 2113.

7. Claims 14, 23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vincent et al. US 4,914,214 in view of Guez et al. US 6,653,336. Guez et al. '336 is 102(e) reference.

Applicants claim a crystalline form of the compound of formula (I), i.e., perindopril of tert-butylamine salt, and its pharmaceutical compositions, see claim 14, 23, and 25-26. The claimed pharmaceutical compositions of claims 25-26 also comprises a diuretic. The instant compositions are used as agents treating cardiovascular diseases.

It is noted that the preamble of the characteristics of the X-ray diffraction data does not obtain any patentability weight.

Determination of the scope and content of the prior art (MPEP §2141.01)

Vincent et al. disclose the same instant compound of same tert-butylamine salt in crystalline form, see column 10, lines 10-31. Guez et al. disclose a pharmaceutical composition tablet comprising a compound, i.e., perindopril of tert-butylamine salt, and a diuretic (i.e., indapamide), see column 4, Examples 1-2.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Vincent et al. or Guez et al. is that Vincent et al. or Guez et al. silence the X-ray diffraction data of the instant compound.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 14, 23, and 25-26 prima facie obvious **because** one would be motivated to employ the compounds/compositions of Vincent et al. or Guez et al. to obtain the instant crystalline form of the compound perindopril of tert-butylamine salt and its pharmaceutical compositions, wherein the instant compound is in a crystalline form and a pharmaceutical compositions also comprising a diuretic. Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the

prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966). Something which is old does not become patentable upon the discovery of a new property, see M.P.E.P. 2112. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed crystalline forms and its compositions of known compounds would have been suggested to one skilled in the art.

The motivation to obtain the claimed crystalline form of the compound perindopril of tert-butylamine salt or its pharmaceutical composition derives from known Vincent et al. or Guez et al. pharmaceutically useful compounds with the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc., would possess similar activities (i.e., agents treating cardiovascular diseases) to that which is claimed in the reference.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 14, 23 and 25-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, and 11-12 of Pfeiffer et al. co-pending application No. 11/052,489. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a crystalline form of the compound of formula (I), i.e., perindopril of tert-butylamine salt, and its pharmaceutical compositions, see claim 14, 23, and 25-26. The claimed pharmaceutical compositions of claims 25-26 also comprises a diuretic. The instant compositions are used as agents treating cardiovascular diseases. It is noted that the preamble of the characteristics of the X-ray diffraction data does not obtain any patentability weight.

Pfeiffer et al. claim a crystalline form the same instant compound perindopril of tert-butylamine salt, and its pharmaceutical compositions. Pfeiffer et al. compositions also comprise a diuretic indapamide. It is noted that the preamble of the characteristics of the X-ray diffraction data of Pfeiffer et al. does not obtain any patentability weight.

The difference between the instant claims and Pfeiffer et al. is that the name of crystalline forms of instant claims and Pfeiffer et al. are different.

One having ordinary skill in the art would find the instant claims 14, 23, and 25-26 prima facie obvious **because** one would be motivated to employ the compounds of Pfeiffer et al. to obtain the instant crystalline form of the compound perindopril of tert-butylamine salt and its pharmaceutical compositions, wherein the instant compound is in a crystalline form and a pharmaceutical compositions comprising a diuretic. Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966). Something which is old does not become patentable upon the discovery of a new property, see M.P.E.P. 2112. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed crystalline forms and its compositions of known compounds would have been suggested to one skilled in the art.

The motivation to obtain the claimed crystalline form of the compound perindopril

of tert-butylamine salt or its pharmaceutical composition derives from known Pfeiffer et al. pharmaceutically useful compounds with the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc., would possess similar activities (i.e., agents treating cardiovascular diseases) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

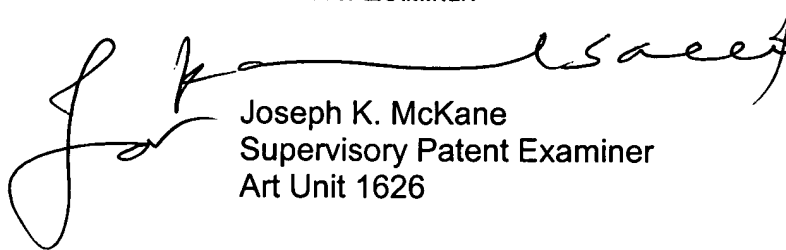
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

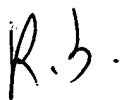
Art Unit: 1626

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Joseph K. McKane', written over the printed name and title.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

A handwritten signature in black ink, appearing to read 'R. Shiao', written over the printed name and title.

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

May 04, 2006